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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,355	10/14/2003	Hanswalter Zentgraf	31304-760.831	6701

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EXAMINER	
DAHLE, CHUN WU	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
07/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Office Action Summary	Application No.	Applicant(s)	
	10/686,355	ZENTGRAF ET AL.	
	Examiner	Art Unit	
	CHUN DAHLE	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-10* is/are pending in the application.

4a) Of the above claim(s) *5-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/19/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 19, 2007, has been entered.

Claims 3 and 4 have been canceled.

Claims 1, 2, and 5-10 are pending.

Claims 5-10 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 25, 2006.

Claims 1 and 2 are currently under consideration.

2. This Office Action is in response to Applicant's amendment to the claims and remarks filed on September 19, 2007.

The rejections of record can be found in the previous Office Actions, mailed on July 7, 2006 and January 23, 2007.

3. Upon further consideration, the previous rejection under 35 U.S.C. 103(a) has been withdrawn.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a *Written Description*, New Matter rejection.

The phrase "wherein said antibody binds specifically to said histidine portion but not to the non-histidine portion of the fusion polypeptide" as recited in claims 1 and 2 is not supported by the original disclosure or claim as filed.

Applicant's amendment, filed November 6, 2006, has added the above described limitation. However, applicant fails to direct support of such amendment in the instant specification and fails to assert that no new matter has been added.

The specification as filed does not provide sufficient written description of the above-mentioned "limitation". The specification does not provide sufficient support for a monoclonal antibody against a fusion polypeptide comprising histidine portion, "wherein said antibody binds specifically to said histidine portion but not to the non-histidine portion of the fusion polypeptide". The specification only discloses antibodies recognize fusion polypeptides comprising a histidine portion as well as monoclonal antibody made from clone ACC2207 that recognizes specifically histidine fusion polypeptides but not polypeptides without histidine portion (see second full paragraph on page 3 and Example 3 on page 6 of the instant specification); the instant claims now recite any monoclonal antibody that binds specifically to said histidine portion but not to the non-histidine portion of the fusion polypeptide, which was not clearly disclosed in the specification. Therefore, the claims represent a departure from the specification and claims originally filed. Applicant's reliance on generic disclosure (antibodies recognize fusion polypeptides comprising a histidine portion) and possibly a single of monoclonal antibody made by clone ACC 2207 do not provide sufficient direction and guidance to the features currently claimed. It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679 683 (CCPA 1972) and MPEP 2163.05.

Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above. See MPEP 714.02, 2163.05-06 and 2173.05 (i).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (Journal of Immunological Methods 1992. 156:231-238, reference on IDS submitted on December 4, 2003) in view of Randall et al. (Vaccine 1993, 11;12:1247-1252, reference on IDS submitted on December 4, 2003) and Harlow et al. (Antibodies. A Laboratory Manual. 1988. pages 139-147, reference on PTO-892 mailed on July 7, 2006).

Evans et al. teach rabbit polyclonal antibodies specifically bind a metal binding peptide His-Asp-His-Asp-His (e.g. see Material and methods on pages 232-233). Evans et al. further teach that said polyclonal antibodies recognize fusion proteins comprising the metal binding peptide but does not recognize proteins lack the metal binding peptide (e.g. see page 231). Furthermore, Evans et al. teach that monoclonal and polyclonal antibodies specific to tags such as metal binding peptide are useful in developing detection and quantitative assays for recombinant proteins as well as tracking intracellular distribution of expressed proteins (e.g. see page 238).

The reference teachings differ from the claimed invention by not exemplifying monoclonal antibody to metal binding peptides comprising 6-18 successive histidine residues.

Randall et al. teach a metal binding peptide that has six successive histidine residues (e.g. see abstract).

Harlow et al. teach that monoclonal antibodies can be made using hybridoma technique and that the advantages of monoclonal antibodies include high specificity in binding, homogeneity, and their ability to be produced in unlimited quantities (see entire document, particularly pages 141-147).

It would thus have been obvious to one skill in art at the time of the invention to combine the elements as claimed (e.g. monoclonal antibody that binds histidine portion but does not bind non-histidine portion) by known methods of making monoclonal antibody taught by Harlow et al. and the use of metal binding peptides taught by Evans et al. with no change in their respective functions and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. Further, substitution of one known metal binding peptide His-Asp-His-Asp-His for another metal binding peptide (e.g. six successive histidine residues) would have yielded predictable results of an antibody that recognize fusion proteins comprising the metal binding peptide but does not recognize proteins lack the metal binding peptide to one of ordinary skill in the art at the time of the invention. Furthermore, given that antibodies recognize mental binding peptide are useful in developing detection and quantitative assays for recombinant proteins and for tracking intracellular distribution of proteins and there is finite number of the mental binding peptides (e.g. His-Asp-His-Asp-His and six successive histidine residues), a person of ordinary skill has good reason to pursue the known options of making monoclonal antibody to metal binding peptides including six successive histidine residues

wherein the antibody does not bind non-histidine portion of the protein within his or her own technical grasp with a reasonable expectation of success.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant argues that Randall et al. teach away from the claimed invention because Randall et al. teach that his-tag is not likely to be immunogenic. This is not found persuasive since the data from Randal et al. clearly show antibody against His tag (e.g. see page 1251).

Applicant further asserts commercial success of the claimed antibody. Thus, applicant argues that any *prima facie* rejection under 35 U.S.C. 103(a) is successfully rebutted.

This is not found persuasive for following reasons:

Objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims. In this case, the evidence showing that the species of antibody made by clone ACC2207 is not commensurate in scope with the broad claims at issue that are directed to the genus of monoclonal antibodies. Further, applicant has not show that the alleged commercial success is directly derived form the invention claimed in a marketplace where the consumer is free to choose on the basis of objective principles, and that such success is not the result of heavy promotion or advertising, shift in advertising, consumption by purchasers normally tied to applicant or assignee, or other business events extraneous to the merits of the claimed invention. Furthermore, applicant has not showed that the claimed features were responsible for the commercial success of kits listed (e.g. Penta-His Alexa Fluo 555 conjugate) on page 11 of the Remarks mailed on September 19, 2007). Moreover, it is noted that gross sales figures do not show commercial success absent evidence as to market share, *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985), or as to the time period during which the product was sold, or as to what sales would normally be expected in the market, Ex parte Standish, 10 USPQ2d 1454 (Bd. Pat. App. & Inter. 1988). Here, applicant merely asserts that several million dollars worth of products has been sold without providing any evidence of market share, time period during which the product was sold.

Therefore, applicant's arguments have not been found persuasive.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone

are unsuccessful, the examiner's supervisor Eileen O'Hara can be reached 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chun Dahle/
Primary Examiner, Art Unit 1644

Chun Dahle, Ph.D. (formerly Chun Crowder)
Patent Examiner
June 27, 2008